

### C. Remarks

The claims are 1-20, with claims 1 and 7 being independent. Claims 7-19 have been withdrawn from consideration as being directed to a non-elected invention.

Reconsideration of the present claims is expressly requested.

Claims 1-6 and 20 stand rejected under 35 U.S.C. § 102 (b) as being allegedly anticipated by U.S. Patent No. 6,167,313 (Gray; WO 97/43005). Claims 1-6 and 20 stand rejected under 35 U.S.C. § 103(a) as being allegedly obvious from Gray or S.A. Gómez-Lopera et al., "Synthesis and Characterization of Spherical Magnetite/Biodegradable Polymer Composite Particles," 240 *J. Colloid. Interface Sci.* 40-47 (2001) (Gómez-Lopera) or Urs O. Häfeli et al., "Effective Targeting of Magnetic Radioactive <sup>90</sup>Y-Microspheres to Tumor Cells by an Externally Applied Magnetic Field. Preliminary In Vitro and In Vivo Results," 22(2) *Nucl. Med. Biol.* 147-55 (1995) (Häfeli) in view of U.S. Patent Application Publication No. 2002/0064844 A1 (Shi). The grounds of rejection are respectfully traversed.

Prior to addressing the merits of rejection, Applicants would like to briefly discuss some of the features of the presently claimed invention. That invention, in pertinent part, is related to a structure containing a PHA and a magnetic substance. Specifically, the present claims recite a dual-phased structure comprising an internal phase (e.g., core), which is contained in an external phase (e.g., shell). The PHA is included in the external phase, and the magnetic material is included in one or both of the external and the internal phase.

Applicants respectfully submit that none of the cited references discloses or suggests a dual-phased structure as presently claimed. Products and processes described in those references provide, at most, a structure containing a magnetic substance in a "single-phase" resin component with no distinguishable external phase part and internal phase part. Furthermore,

Applicants respectfully submit that even in theory, it would be very difficult, if not impossible, to obtain a structure with a monomer unit composition of a PHA varying in a direction from the inside toward the outside of the structure, as recited in present claim 5, using the processes described in the cited references. Furthermore, Gómez-Lopera and Häfeli teach the use of polylactic acid (PLA) as a resin constituting their structures, and PLA is a substantially different compound from the PHA.

In order to highlight the differences between the presently claimed structure and the structures in the cited references, Applicants would like to direct the Examiner's attention to the following illustrative diagrams.

Diagram 1:

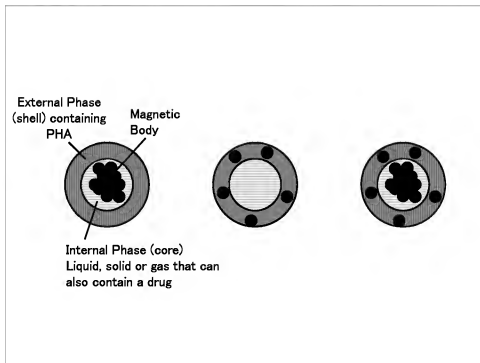


Diagram 1 schematically represents various exemplary structures in accordance with the present invention. In this diagram, small circular dots in solid black represent magnetic bodies. Each drawing in Diagram 1 depicts a different embodiment of the present invention,

showing a different location of the magnetic material. Thus, the inventive structure, as shown above, is dual-phased and comprises, for example, a core contained in a shell. In each embodiment, the shell contains the PHA, while the core can be in a solid, liquid or gas phase and may contain other chemicals as desired.

Diagram 2:

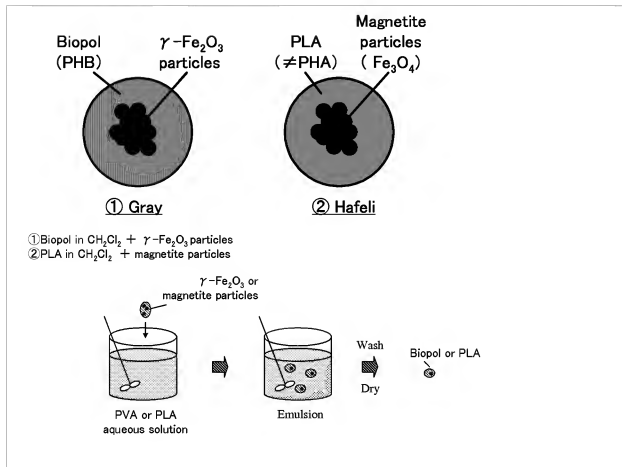


Diagram 2 shows the structures and processes for preparing the structures as disclosed in Gray and Häfeli. In accordance with Gray, a solution of Biopol in dichloromethane and  $\gamma\text{-Fe}_2\text{O}_3$  particles are added into an aqueous PVA solution, and the resulting mixture is stirred to form an emulsion. The encapsulated material in Gray is then obtained from the

emulsion through subsequent washing and drying steps (see col. 9, lines 6-13). The structure in Häfeli is obtained by substantially the same process, except a PLA solution in methylene chloride and magnetite particles are used in lieu of the Biopol solution in dichloromethane and  $\gamma$ - $\text{Fe}_2\text{O}_3$  particles (see page 148 – preparation of radioactive magnetic microspheres).

As a result, in Gray,  $\gamma$ - $\text{Fe}_2\text{O}_3$  particles are encapsulated in Biopol (PHB). In the structure of Häfeli, magnetite ( $\text{Fe}_3\text{O}_4$ ) particles are encapsulated in PLA. As is clearly demonstrated in Diagram 2, these are not dual-phase structures as presently claimed.

Diagram 3:

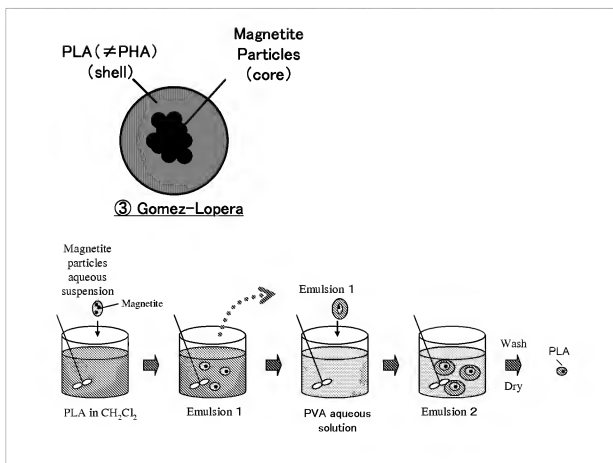


Diagram 3 shows the structure and the process for its preparation in accordance with Gómez-Lopera. In Gómez-Lopera, an aqueous suspension of magnetite particles is added with stirring into a PLA solution in dichloromethane to obtain a first emulsion. The first emulsion is then added into an aqueous PVA solution to form a second emulsion. Then, the product is obtained from the second emulsion through subsequent washing and drying steps (see page 41).

Thus, in the structure disclosed in Gómez-Lopera, magnetite particles form a core, which is encapsulated in a PLA shell. As is clearly shown above, this is also not a dual-phase structure as presently claimed.

Shi cannot cure the deficiencies of Gray, Häfeli and Gómez-Lopera. Applicants believe that the Examiner cited Shi for a teaching of interchangeability of various biodegradable polymers. Even if assumed, *arguendo*, that Shi contains such a teaching, Shi, like the other cited references, does not disclose or suggest a two-phase structure as presently claimed.

In conclusion, Applicants respectfully submit that the cited references, whether considered separately or in any combination, fail to disclose or suggest all of the presently claimed elements. Wherefore, allowance of the application and expedient passage to issue are therefore respectfully requested.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should be directed to our address given below.

Respectfully submitted,

/Jason M. Okun/  
Jason M. Okun  
Attorney for Applicants  
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO  
30 Rockefeller Plaza  
New York, New York 10112-3801  
Facsimile: (212) 218-2200

FCHS\_WS 2112389\_1.DOC